



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,454	02/08/2005	Monique Berwac	2004_0980A	2307
513	7590	04/06/2006	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P.			SILVERMAN, ERIC E	
2033 K STREET N. W.			ART UNIT	
SUITE 800			PAPER NUMBER	
WASHINGTON, DC 20006-1021			1615	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/500,454	Applicant(s) BERWAER ET AL.	
	Examiner Eric E. Silverman, PhD	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11-30-08</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Receipt of Applicant's response to Notice of Non-compliant amendment, filed 2/2/2006 is acknowledged.

Claims 1 – 6 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In light of amendment, the rejection of claim 4 as indefinite under the second paragraph of 35 U.S.C. 112 is withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments regarding the rejection of claims 1 – 6 under 35 USC 103(a) as unpatentable over Guy (US 3,906,086) in combination with Kreutner (US 5,869,479) is persuasive. This rejection is withdrawn.

Claims 1 – 5 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,464,376 to Sunshine in combination with Kreutner.

Sunshine teaches a composition that allows for both the extended and immediate release of an active agent (col. 16, lines 16 – 26). Sunshine further teaches use of the appropriate amount of the active agent of interest, and that the amount of agent will

Art Unit: 1615

depend on the agent chosen (col. 17, lines 1 – 21). The agents of Sunshine are anti-inflammatory medicaments.

Sunshine does not teach the use of efletirizine.

Kreutner teaches methods and compositions for relief from symptoms of rhinitis by treatment with a combination of H1 and H3 receptor antagonists. Note that rhinitis is an inflammation of the mucosa. Eftirizine is among the active agents mentioned (claim 4). Since Eftirizine is taught to treat an inflammatory disorder, it is also an anti-inflammatory medicament.

Accordingly, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use efletirizine in the dosage form of Sunshine. The motivation to do so comes from Kreutner, who teaches the utility of efletirizine for treatment of inflammations associated with rhinitis. It would be within the skill of the art to choose the most appropriate combination of medicaments from those listed in Kreutner, since Kreutner specifically teaches the combination of two medicaments and exemplifies efletirizine by listing it in a claim. Since Sunshine teaches use of anti-inflammatory medicaments, the artisan would have a reasonable expectation of success. The expected result would be a dosage form with a combination of controlled and immediate release of efletirizine.

Applicant's arguments have been fully considered, but are not persuasive.

With respect to the argument that Examiner "cherry-picked" portions of the patents relied upon, specifically the active agent, it is noted that the active agent of instant invention is mentioned in the claims of Kreutner. Accordingly, the selection of

efletirizine cannot be said to be "cherry-picking", since efletirizine is clearly an important aspect of Kreutner's invention, as evidenced by inclusion of efletirizine in the claims. An element mentioned in the claims of a patent cannot be said to be an unimportant, non-preferred, or non-exemplified element.

Claim 6 **remains** rejected under 35 U.S.C. 103(a) as being unpatentable for reasons of record.

Applicant's arguments have been fully considered but are not persuasive. Applicant offers no arguments in addition to those mentioned with respect to the combination of Sunshine and Kreutner. Those arguments have been addressed, *supra*.

Conclusion

US 4,966,147 is noted for the teaching that rhinitis is an inflammation.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1615

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric E. Silverman, PhD
Art Unit 1615



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600